IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ogle et al.
Serial No.: 10/554,122
Filed: 09/11/2006
Group No.: 1637
Examiner: Strzelecka
Entitled: **METHODS FOR ASSESSING BIOLOGIC DIVERSITY**

DECLARATION OF JEFFREY L. PLATT, MD UNDER 37 C.F.R. § 1.131

EFS Web Filed
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Strzelecka:

I, Jeffrey L. Platt, hereby declare and state, under penalty of perjury, that:

1. I am one of the inventors of the above-named patent application (hereinafter "present application").

2. It is my understanding that in the Office Action mailed October 13, 2009, the Examiner has cited as prior art a PCT publication to Gehrmann *et al.* (WO03/044225, filed November 15, 2002). On page 3 of the Office Action, the Examiner cites Gehrmann et al. against Claim 1 of the present application as follows:

A) Regarding claim 1, Gehrmann et al. teach a method of determining lymphocyte diversity in a subject, the method comprising:

a) providing:

i) labeled nucleic acid molecules from a population of said subject's lymphocytes, wherein each of said labeled nucleic acid molecule encodes a lymphocyte receptor or a portion thereof (page 9, lines 24-30; page 11, lines 17-31; page 12; page 13, lines 1-9; page 19, lines 7-10),

ii) a population of nucleic acid molecules, wherein said population of nucleic acid molecules comprises random nucleic acid molecules or unselected express sequence tags (page 13, lines 11-19);

b) hybridizing said labeled nucleic acid molecules or fragments of said labeled nucleic acid molecules with said population nucleic acid molecules (page 13, lines 11-19; page 17, lines 1-5; page 19, lines 12-14);

c) assessing hybridization of said labeled RNA nucleic acid molecules with said population of nucleic acid molecules to determine the frequency of hybridization (page 13, lines 24-29; page 29, lines 17-20), and

d) quantifying the amount lymphocyte diversity in said subject (page 13, lines 24-29; page 14, lines 29-30; page 15, lines 1-2).

3. Attached at TAB A is an invention disclosure form that is prior to the November 15, 2002 filing date of the Gehrmann et al. reference. This invention disclosure form shows, at paragraph 2, that the inventors of the present application described the material cited from Gerhrmann et al. (above), and found in Claim 1, prior to the November 15, 2002 filing date of Gehrmann et al. It is noted that the gray boxes on the invention disclosure form represent redacted material.

4. I further declare that all statements made herein are of my own knowledge, are true, and that all statements are made on information and belief that are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application of any patent issued thereon.

Dated: 3/11/10

Jeffrey L. Platt, MD

Confidential

Invention & Assignment Record

1. **Title of Invention:**
   Measurement of Lymphocyte Receptor Diversity using a Gene Chip

2. **Invention Description:**
   Immune competence is thought to be related to lymphocyte receptor diversity. There is currently no reliable way to measure lymphocyte receptor diversity. We propose here a method to measure lymphocyte receptor diversity using gene chips. RNA is extracted from peripheral blood lymphocytes or tissue samples. RNA coding for lymphocyte receptors is isolated and labeled with a detectable moiety. The labeled sample is then hybridized to a gene chip. The gene chip could be either a currently available chip containing know sequences or a chip we would design containing random sequences. The degree of hybridization (i.e., the number of RNA fragments bound to oligos on the chip) is indicative of the level of individual lymphocyte receptor diversity.

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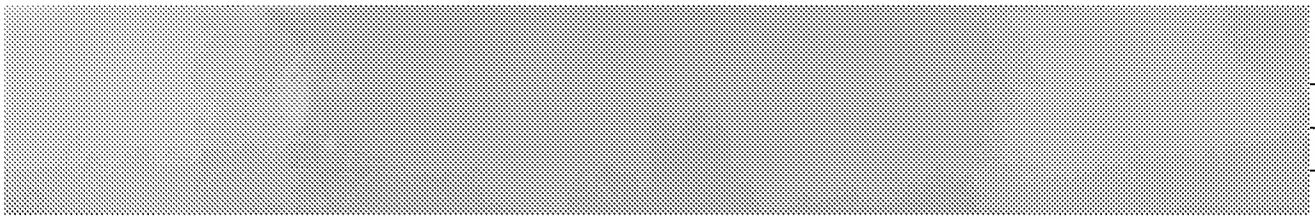
8. **Prototype:**

____ Yes ____ No ____ Not Applicable

Developed by: Organization and Engineers

9. 

10. **Recommended Invention Evaluators:**

Organization and Contact

Organization and Contact

11. **Potential Licensees:**

Organization and Contact

Organization and Contact

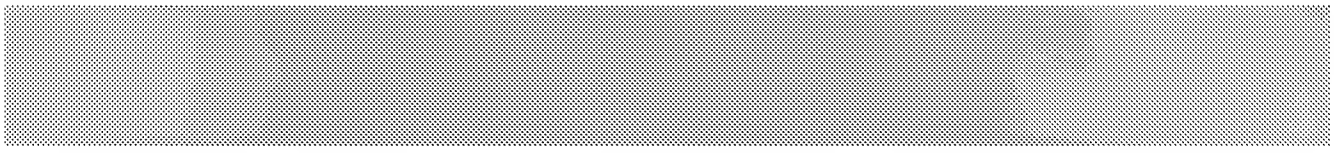
12. **Additional Information Useful in Evaluating the Invention:**

REQUIRED ATTACHMENTS

13. **Confidential Description:** ____ Attached ____ Not Applicable/Not Available

Attach a detailed, technical description of the invention, with photographs, drawings, sketches or any other descriptive material as appropriate. The description should be as detailed as possible and should include the construction, chemical structure or composition components, the principles involved, the details of operation and alternative methods of construction, formulation or operation if known. The description should cover the following points:

(a) Problem to be solved or purpose of invention
(b) How the invention solves the problem and advantages the invention has over current methods
(c) Related technologies in current use or old manner of performing the function of the invention
(d) Disadvantages of existing technologies
(e) Current status of the invention development

14. 

15. **Background Materials:** ____ Attached ____ Not Applicable/Not Available

Attach copies of key publications, manuscripts or other descriptions of the invention in progress by you or others that provide a background to the current state of knowledge in the field of the invention.

16.

17. **Inventor Information – Mayo Inventors Only:** *(see back page for additional Inventor Information if necessary)*

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18.

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Submit Completed Invention & Assignment Record to:

Mayo Medical Ventures
Office of Technology Commercialization
Centerplace 4

See *"Instructions on using the Invention & Assignment Record"* for Additional Information

mayo

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